

We claim:

1. A method of treating at least one diagnosed pelvic floor disorder in a  
5 patient, the at least one disorder being selected from the group consisting of urinary voiding dysfunction, fecal voiding dysfunction, constipation, stress incontinence, urge incontinence, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatic pain and prostaticodynia, the method comprising:
  - 10 providing an hermetically sealed implantable electrical pulse generator configured to provide at least first and second electrical stimulation pulse regimes via at least first and second implantable medical electrical leads;  
providing the first implantable medical electrical lead, the first lead being configured for implantation adjacent, around or in at least one of a sacral nerve  
15 or branches or portions thereof, the first lead comprising proximal and distal ends and at least a first electrode;  
providing the second implantable medical electrical lead, the second lead being configured for implantation adjacent a pudendal nerve or branches or portions thereof, the second lead comprising proximal and distal ends and at  
20 least a second electrode;  
implanting the first lead in or near a first tissue volume of the patient adjacent, around or in one of the sacral nerve or branches or portions thereof;  
implanting the second lead in or near a second tissue volume of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof;  
25 operably connecting the proximal end of the first lead to the implantable pulse generator;  
operably connecting the proximal end of the second lead to the implantable pulse generator;  
implanting the implantable pulse generator within the patient; and  
30 delivering, from the implantable pulse generator, first electrical stimulation pulses to or near at least portions of the first tissue volume through the first lead

and at least the first electrode, the first pulses being provided in accordance with the first electrical stimulation pulse regime;

delivering, from the implantable pulse generator, second electrical stimulation pulses to or near at least portions of the second tissue volume through the

5 second lead and at least the second electrode, the second pulses being provided in accordance with the second electrical stimulation pulse regime;

wherein the combination of the first and the second electrical pulse regimes delivered through the first and second leads to or near at least portions of the first and second tissue volumes provides to the patient at least partial relief from the  
10 pelvic floor disorder.

2. The method of claim 1, wherein at least one of the first lead and the second lead is selected from the group consisting of a unipolar lead, a bipolar lead, a tri-polar lead, a quadrapolar lead, and a multi-polar lead.

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3. The method of claim 1, wherein at least one of the first lead and the second lead is selected from the group consisting of a beam steering lead comprising multiple electrodes and a lead comprising multiple electrodes disposed in an areal pattern on a planar or curved surface.

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4. The method of claim 1, wherein at least one of the first lead and the second lead is selected from the group consisting of a cuff lead, a paddle lead, a tined lead, a lead having an active fixation device or member disposed thereon, attached thereto or forming a portion thereof.

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5. The method of claim 1, wherein at least one of the first lead and the second lead comprises a fixation mechanism selected from the group consisting of a suture sleeve, a barb, a helical screw, a hook and a tissue in-growth mechanism.

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6. The method of claim 1, wherein at least one of the first lead and the second lead further comprises one or more electrodes configured to operate in conjunction with an electrically conductive portion of the implantable pulse generator acting as an indifferent electrode.

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7. The method of claim 1, further comprising delivering electrical pulses through a third tissue volume disposed near or between the electrodes located on the first and second leads.

10 8. The method of claim 1, wherein the electrical stimulation pulses that are delivered to the first and second tissue volumes cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion.

15 9. The method of claim 1, further comprising providing a lead extension, operably connecting same between one of the proximal end of the at least first lead and the proximal end of the at least first lead, and the implantable pulse generator, and delivering the electrical stimulation pulses through the lead extension.

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10. The method of claim 1, wherein at least one of the first lead and the second lead is selected from the group consisting of a lead comprising a lead body less than about 5 mm in diameter, a lead comprising a lead body less than about 1.5 mm in diameter, a lead having a lead body comprising polyurethane or  
25 silicone, a lead comprising electrical conductors disposed within the body thereof and extending between the proximal and distal ends of the lead wherein the conductors are formed of coiled, braided or stranded wires, and a lead comprising at least one ring electrode, at least one coiled electrode, at least one button electrode, at least one electrode formed from a portion of wire, a cuff, a  
30 barb or a hook, a spherically-shaped electrode, and a helically-shaped electrode.

11. The method of claim 1, wherein an inter-electrode distance of at least one of the first lead and the second lead is selected from the group consisting of about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, about 9 mm, about 10 mm, about 12 mm, about 14 mm, about 16 mm, about 18 mm, about 20 mm, about 25 mm, and about 30 mm.

12. The method of claim 1, wherein the at least one electrode of at least one of the first lead and the second lead has an electrode surface area ranging between about 1.0 sq. mm and about 100 sq. mm, between about 2.0 sq. mm and about 50 sq. mm, or between about 4.0 sq. mm and about 25 sq. mm.

13. The method of claim 1, wherein the distance between the proximal and distal ends of at least one of the first lead and the second lead is selected from the group consisting of less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches.

14. The method of claim 1, wherein the implantable pulse generator comprises an electronic circuitry architecture selected from the group consisting of a microprocessor-based architecture, a logic architecture and a state machine architecture.

15. The method of claim 1, further comprising providing an external programming unit and effecting telemetric communication between the programming unit and the implantable pulse generator.

16. The method of claim 1, wherein the implantable pulse generator further comprises at least one of a primary battery power source and a secondary battery power source.

17. The method of claim 1, wherein the implantable pulse generator is configurable so as to permit at least one of the frequency, rate, amplitude, phase, width and morphology of the pulses generated and delivered by the implantable pulse generator to be varied programmably by a user.

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18. The method of claim 1, wherein at least one of the first lead and the second lead is configured for percutaneous introduction and implantation within the patient.

10 19. The method of claim 1, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and delivering electrical pulses having frequencies ranging between about 50 Hz and about 100 Hz, between about 10 Hz and about 250 Hz, and between about 0.5 Hz and about 500 Hz.

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20. The method of claim 1, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and delivering electrical pulses having amplitudes ranging between about 1 Volt and about 10 Volts, between about 0.5 Volts and about 20 Volts, and between about 0.1 Volts and about 50 Volts.

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21. The method of claim 1, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and delivering electrical pulses having pulse widths ranging between about 180  
25 microseconds and about 450 microseconds, between about 100 microseconds and about 1000 microseconds, and between about 10 microseconds and about 5000 microseconds.

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22. The method of claim 1, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and delivering electrical pulses having varying spatial or temporal phases.

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23. The method of claim 1, further comprising delivering a drug to the patient.

24. The method of claim 23, further comprising providing, implanting and  
5 activating an implantable drug pump for providing the drug to the patient.

25. The method of claim 1, wherein at least one of activation, modification and termination of at least one of the first pulse regime and the second pulse regime is carried out by the patient or a health care giver.

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26. The method of claim 25, wherein the at least one of activation, modification and termination of at least one of the first pulse regime and the second pulse regime is carried out in response to patient symptoms appearing or disappearing, or the patient feeling or not feeling symptoms

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27. The method of claim 25, wherein patient or health care giver activation, modification and/or termination of the first or second pulse regime is accomplished through infra-red, telemetric, radio, magnetic, or ultrasonic means.

20 28. The method of claim 1, wherein the first pulse regime is delivered while delivery of the second pulse regime is initiated later in response to a sensed physical parameter or symptom.

25 29. The method of claim 1, wherein the first and second pulse regimes are initially delivered, and delivery of at least one of the first and second pulse regimes is subsequently terminated or modified.

30 30. The method of claim 1, wherein at least one of the first pulse regime and the second pulse regime is one of activated, modified and terminated in response to a physical parameter or symptom being sensed.

31. The method of claim 30, wherein the physical parameter is sensed using a sensor selected from the group consisting of a bladder pressure sensor, a leak sensor, a volume sensor, a urinary volume or pressure sensor, a urinary impedance sensor, a nerve electrical signal sensor, and an electromyographic sensor.

32. A method of treating at least one diagnosed pelvic floor disorder in a patient, the at least one disorder being selected from the group consisting of urinary voiding dysfunction, fecal voiding dysfunction, constipation, stress incontinence, urge incontinence, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostaticgia and prostaticdynia, the method comprising:

providing a first hermetically sealed implantable electrical pulse generator configured to provide at least a first electrical stimulation pulse regime via at least a first implantable medical electrical lead;

providing a second hermetically sealed implantable electrical pulse generator configured to provide at least a second electrical stimulation pulse regime via at least a second implantable medical electrical lead;

providing the first implantable medical electrical lead, the first lead being configured for implantation adjacent, around or in at least one of a sacral nerve or branches or portions thereof, the first lead comprising proximal and distal ends and at least a first electrode;

providing the second implantable medical electrical lead, the second lead being configured for implantation adjacent a pudendal nerve or branches or portions thereof, the second lead comprising proximal and distal ends and at least a second electrode;

implanting the first lead in or near a first tissue volume of the patient adjacent, around or in one of the sacral nerve or branches or portions thereof;

implanting the second lead in or near a second tissue volume of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof;

operably connecting the proximal end of the first lead to the first implantable pulse generator;

operably connecting the proximal end of the second lead to the second implantable pulse generator;

- 5        implanting the first implantable pulse generator within the patient;  
         implanting the second implantable pulse generator within the patient;  
         and

         delivering, from the first implantable pulse generator, first electrical stimulation pulses to or near at least portions of the first tissue volume through the first lead  
10        and at least the first electrode, the first pulses being provided in accordance with the first electrical stimulation pulse regime;

         delivering, from the second implantable pulse generator, second electrical stimulation pulses to or near at least portions of the second tissue volume through the second lead and at least the second electrode, the second pulses  
15        being provided in accordance with the second electrical stimulation pulse regime;

         wherein the combination of the first and the second electrical pulse regimes delivered through the first and second leads to or near at least portions of the first and second tissue volumes provides to the patient at least partial relief from the pelvic floor disorder.

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33.    The method of claim 32, wherein at least one of the first lead and the second lead is selected from the group consisting of a unipolar lead, a bipolar lead, a tri-polar lead, a quadrapolar lead, and a multi-polar lead.

25    34.    The method of claim 32, wherein at least one of the first lead and the second lead is selected from the group consisting of a beam steering lead comprising multiple electrodes and a lead comprising multiple electrodes disposed in an areal pattern on a planar or curved surface.

30    35.    The method of claim 32, wherein at least one of the first lead and the second lead is selected from the group consisting of a cuff lead, a paddle lead, a



tined lead, a lead having an active fixation device or member disposed thereon, attached thereto or forming a portion thereof.

36. The method of claim 32, wherein at least one of the first lead and the  
5 second lead comprises a fixation mechanism selected from the group consisting of a suture sleeve, a cuff, a barb, a helical screw, a hook and a tissue in-growth mechanism.

37. The method of claim 32, wherein at least one of the first lead and the  
10 second lead further comprises one or more electrodes configured to operate in conjunction with an electrically conductive portion of the implantable pulse generator acting as an indifferent electrode.

38. The method of claim 32, further comprising delivering electrical pulses  
15 through a third tissue volume disposed near or between the electrodes located on the first and second leads.

39. The method of claim 32, wherein the electrical stimulation pulses that are  
20 delivered to the first and second tissue volumes cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion.

40. The method of claim 32, further comprising providing a lead extension,  
operably connecting same between one of the proximal end of the at least first  
25 lead and the proximal end of the at least first lead, and the implantable pulse generator, and delivering the electrical stimulation pulses through the lead extension.

41. The method of claim 32, wherein at least one of the first lead and the  
30 second lead is selected from the group consisting of a lead comprising a lead body less than about 5 mm in diameter, a lead comprising a lead body less than

about 1.5 mm in diameter, a lead having a lead body comprising polyurethane or silicone, a lead comprising electrical conductors disposed within the body thereof and extending between the proximal and distal ends of the lead wherein the conductors are formed of coiled, braided or stranded wires, and a lead  
5 comprising at least one ring electrode, at least one coiled electrode, at least one button electrode, at least one electrode formed from a portion of wire, a barb or a hook, a spherically-shaped electrode, and a helically-shaped electrode.

42. The method of claim 32, wherein an inter-electrode distance of at least  
10 one of the first lead and the second lead is selected from the group consisting of about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, about 9 mm, about 10 mm, about 12 mm, about 14 mm, about 16 mm, about 18 mm, about 20 mm, about 25 mm, and about 30 mm.

15 43. The method of claim 32, wherein the at least one electrode of at least one of the first lead and the second lead has an electrode surface area ranging between about 1.0 sq. mm and about 100 sq. mm, between about 2.0 sq. mm and about 50 sq. mm, or between about 4.0 sq. mm and about 25 sq. mm.

20 44. The method of claim 32, wherein the distance between the proximal and distal ends of at least one of the first lead and the second lead is selected from the group consisting of less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches.

25 45. The method of claim 32, wherein the implantable pulse generator comprises an electronic circuitry architecture selected from the group consisting of a microprocessor-based architecture, a logic architecture and a state machine architecture.

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46. The method of claim 32, further comprising providing an external programming unit and effecting telemetric communication between the programming unit and the implantable pulse generator.

5 47. The method of claim 32, wherein the implantable pulse generator further comprises at least one of a primary battery power source and a secondary battery power source.

10 48. The method of claim 32, wherein the implantable pulse generator is configurable so as to permit at least one of the frequency, rate, amplitude, phase, width and morphology of the pulses generated and delivered by the implantable pulse generator to be varied programmably by a user.

15 49. The method of claim 32, wherein at least one of the first lead and the second lead is configured for percutaneous introduction and implantation within the patient.

20 50. The method of claim 32, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and delivering electrical pulses having frequencies ranging between about 50 Hz and about 100 Hz, between about 10 Hz and about 250 Hz, and between about 0.5 Hz and about 500 Hz.

25 51. The method of claim 32, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and delivering electrical pulses having amplitudes ranging between about 1 Volt and about 10 Volts, between about 0.5 Volts and about 20 Volts, and between about 0.1 Volts and about 50 Volts.

30 52. The method of claim 32, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and

delivering electrical pulses having pulse widths ranging between about 180 microseconds and about 450 microseconds, between about 100 microseconds and about 1000 microseconds, and between about 10 microseconds and about 5000 microseconds.

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53. The method of claim 32, wherein the implantable pulse generator and at least one of the first lead and the second lead are capable of generating and delivering electrical pulses having varying spatial or temporal phases.

10 54. The method of claim 32, further comprising delivering a drug to the patient.

55. The method of claim 54, further comprising providing, implanting and activating an implantable drug pump for providing the drug to the patient.

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